

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS (Boston)**

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| IN RE: NEW ENGLAND COMPOUNDING PHARMACY CASES |) | Master Docket No. 1:12-cv-12052 |
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| LANCE MARTIN, TOBY MARTIN and All Other Persons Similarly Situated, |) | |
| |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | Civil Action No. |
| |) | 1:12-cv-12055-FDS |
| NEW ENGLAND COMPOUNDING, PHARMACY, INC., ALAUNUS PHARMACEUTICAL, LLC and AMERIDOSE, LLC, |) | |
| |) | |
| |) | |
| Defendants. |) | |

**PLAINTIFFS' OPPOSITION TO DEFENDANT ALANUS PHARMACEUTICAL'S
MOTION TO DISMISS and TO DEFER RULING**

Now come the Plaintiffs in the above-captioned matter who hereby submit their Opposition to Defendant Alanus Pharmaceutical's Motion to Dismiss for Failure to State a Claim Pursuant to Fed.R.Civ.P. 12(B)6. As grounds in support of their Opposition, Plaintiffs set forth the following. The Plaintiffs also respectfully request that in the interest of Judicial economy and consistency, that the Court defer ruling until ALL Oppositions to ALL Motions to Dismiss by Defendant Alanus have been filed and considered.

Background & Factual Allegations

The Plaintiffs' Amended Complaint alleges (in part) that:

1. NECC, Alaunus and Ameridose are engaged in interstate commerce throughout the United States and provide products and services, in the sale and distribution of various drug and pharmaceutical compounds, including Methylprednisone Acetate, a prescription steroidal medication provided in liquid form and then requiring an injection for administration.
2. Upon information and belief, at various and diverse time, NECC, Alaunus and Ameridose shared facilities and/or employees, in the sale and distribution of various regulated drug and pharmaceutical compounds, including but not limited to, Methylprednisone Acetate, a prescription steroidal medication provided in liquid form and then requiring an injection for administration, and shared common distribution for their products..
3. NECC, Alaunus and Ameridose share common officers and managers, including Gregory Conigliaro and Barry Cadden, and upon information and belief, share common employees and pharmacists in their operations, including the manufacture, distribution and sale of various compounded products and medications.
4. Upon information and belief, at all relevant time, NECC, Alaunus and Ameridose jointly participated in the development, sale, marketing and distribution of compounded medications and products throughout several states within the United States.
5. Upon information and belief, Ameridose and/or Alaunus supplied NECC with various components of compounded medications for use and sale in compounded products, and actively supported and supervised NECC in its business activities, including the production, compounding, testing, inspecting, marketing, sale and distribution of compounded products.
6. Upon information and belief, Ameridose and/or Alaunus employees actively participated in NECC production activities and were assigned, at various and diverse times, to work at the NECC facility in Framingham, MA, including but not limited to supervising, supporting, assisting, compounding, manufacturing, selling and distributing various compounded products, including Methylprednisone Acetate.

7. At various and diverse times herein, NECC, in conjunction with and supported by Ameridose and/or Alaunus, distributed Methylprednisone Acetate in its liquid form contained in a vial that was contaminated with a fungal agent, to wit: Aspergillus and other fungal contaminants and agents, which were capable of producing and causing spinal meningitis.
8. Spinal meningitis is an infection of the meninges located in the spinal cord and central nervous system which may have devastating health effects, including death, significant infection, and significant effects upon body functions and systems.
9. On September 10, 2012, Mr. Martin received an injection of Defendants' Methylprednisone Acetate Product at the Greenspring Surgery Center, 2700 Quarry Lake Drive, Baltimore, MD 21209.
10. On October 4, 2012, the United States Food and Drug Administration (FDA) and the Center for Disease Control (CDC) issued a recall alert to the members of the public stating the NECC had distributed several lots of Methylprednisone Acetate that had been placed in commerce by NECC were contaminated with Aspergillus fungus and/or other contaminants.
11. Upon information and belief, these compounded medications have been distributed throughout various places within the United States and throughout the various states of the United States.
12. Upon information and belief, approximately sealed 18,000 vials of Methylprednisone Acetate (placed in commerce by NECC and Ameridose) were subject to this recall.
13. Recent reports have indicated that the FDA and its inspectors have observed fungal contamination by direct microscopic examination of foreign matter taken from a sealed vial at Methylprednisone Acetate collected from the NECC facility.
14. Mr. Martin was notified by Greenspring Surgery Center that he was exposed to Defendants' contaminated compounded medication Methylprednisone Acetate.

15. On October 5, 2012, the CDC and FDA recommended that all physicians and healthcare professionals cease use of and remove all NECC products, including Methylprednisone Acetate. At or about the same time, NECC and Ameridose ceased operations and production at their facilities, predicated upon inspections of those facilities to determine the extent of contamination in Ameridose and NECC facilities and products.

16. Upon information and belief, over 13,000 patients, including the Plaintiff Lance Martin, were injected with contaminated compounded Methylprednisone Acetate from the affected lots, thus exposing Mr. Martin and other persons similarly situated to the risk of fungal spinal meningitis.

17. This action is brought by the Plaintiffs on behalf of themselves and all other persons similarly situated whose joinder in this action is impractical for the following reasons:

- i. According to reports, there appears to be in excess of 13,000 individuals who have been exposed to the contaminated medications distributed by the NECC, Alaunus and Ameridose over many states and territories within the United States; and
- ii. there are questions of law and fact common to the class in the following respects, including but not limited to: common issues related to the production, inspection and distribution of the contaminated Methylprednisone Acetate marketed, distributed and sold by NECC, Alaunus and Ameridose; common issues related to the conduct of NECC, Alaunus and Ameridose in the quality and control of the production of medications and compounded products; common issues related to the distribution of the offending product; common issues related to injuries or claims suffered by the Plaintiffs, including the risk of meningitis, the emotional distress suffered as the result of said risk, and common issues regarding the necessity for continued medical treatment and monitoring for all class members.

18. The claims of the Plaintiffs Lance Martin and Toby Martin are representative and typical of the claims of the class to whom they seek to represent in that Mr. Martin was exposed by injection to the contaminated Methylprednisone Acetate sold, marketed and distributed by NECC, Alaunus and Ameridose and that he has undergone emotional distress and suffering as a result of said exposure, and requires medical monitoring as a result of said exposure and that Mrs. Martin, as his wife, has sustained a loss of consortium as a result of said exposure to her husband.
19. The representative parties will fairly and adequately protect the interests of the class in the following respects: they will vigorously pursue a lawsuit within the Commonwealth of Massachusetts and have standing and jurisdiction to file same.
20. These common questions of fact, presented in this action, predominate over individual issues and the action is best managed as a class action because the actions and inactions of the Defendants have affected a wide number of plaintiffs spread throughout the country, this making litigation and trial of individual claims unduly burdensome to resolution and fraught with difficulties and inconsistent results.

Standard of Review

In considering the Defendant's Motion to Dismiss, the standard of review is well settled. The Court is required to view the evidence in the light most favorable to the Plaintiff. Simply stated, the Court must answer one question: If the allegations made are accepted as true, do they set forth a valid claim against the Defendant? If they do, the Court must deny the Defendant's Motion to Dismiss.

The Defendant also concedes that the Court must take as true 'the allegations of the complaint, as well as such inferences as may be drawn

therefrom in the plaintiff's favor ...' Blank v. Chelmsford Ob/Gyn, P.C., 420 Mass. 404, 407, 649 N.E.2d 1102 (1995). In evaluating the allowance of a motion to dismiss, the Court is to be guided by the principle that a Complaint is sufficient 'unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.' Nader v. Citron, 372 Mass. 96, 98, 360 N.E.2d 870 (1977), quoting Conley v. Gibson, 355 U.S. 41, 45–46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957).” Warner–Lambert Co. v. Execuquest Corp., 427 Mass. 46, 47, 691 N.E.2d 545 (1998).” The Plaintiffs’ Amended Complaint clearly exceeds this standard.

The Amended Complaint identifies with specificity the negligent acts, errors and or/ omissions committed by Defendant Alanus (as well as NECC and Ameridose). Moreover, the Amended Complaint makes specific allegations of emotional harm and trauma that Defendant Alanus’ negligence caused to the Plaintiff, his wife and others similarly situated. These allegations set forth sufficient basis to survive a Motion to Dismiss and therefore, Defendant Alanus’ Motion to Dismiss must be denied.

Nature of Injury Alleged

Defendant Alanus seems to argue that the Plaintiffs' claim must be dismissed because there has not been an actual allegation of a physical injury. This is simply not the law.

The Supreme Judicial Court has specifically held that under Massachusetts tort law, a plaintiff seeking future damages for medical monitoring following exposure to hazardous substances must prove that “(1) [t]he defendant's negligence (2) caused (3) the plaintiff to become exposed to a hazardous substance that produced to a degree that substantially increased the risk of serious disease, illness, or injury (4) for which an effective medical test for reliable early detection exists, (5) and early detection, combined with prompt and effective treatment, will significantly decrease the risk of death or the severity of the disease, illness or injury, and (6) such diagnostic medical examinations are reasonably (and periodically) necessary, conformably with the standard of care, and (7) the present value of the reasonable cost of such tests and care, as of the date of the filing of the complaint.” *Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215, 226 (2009). All of these factors apply to contraction of meningitis as a result of a tainted injection.

Conclusion

Notwithstanding the strength of Plaintiff's argument to defeat Defendant's Motion to Dismiss, it is important to note that there has been virtually no discovery in this case. Indeed, initial disclosures have not yet been exchanged. At the very least it is clear that the Plaintiffs' claims should be permitted to survive through discovery. Based upon the foregoing, the Plaintiffs respectfully request that the Court DENY the Defendant Alanus' Motion to Dismiss.

Furthermore, since Alanus has filed several Motions to Dismiss in other related cases whose Oppositions are due in the upcoming days and weeks, the Plaintiffs also respectfully request that in the interest of Judicial economy and consistency, that the Court defer ruling until ALL Oppositions to ALL Motions to Dismiss by Defendant Alanus have been filed and considered.

Respectfully Submitted:

Plaintiffs,
Lance Martin, et al.

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Certificate of Service

I, Frank J. Federico, Jr., hereby certify that I served a copy of the foregoing document upon all counsel of record by causing a copy to be sent to them via the Electronic Filing System this 24th day of January, 2013.

/s/ Frank J. Federico, Jr.

Frank J. Federico, Jr.